

**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

**IN RE: NEW ENGLAND
COMPOUNDING PHARMACY
CASES**

Master Docket No.
12-12052-FDS

This Document Relates To:

**RAYMOND MCDOW, ROSEANNE BROOKS,
et. al.,**

Plaintiffs,

Civil Action No.
12-12112-FDS

V.

**NEW ENGLAND COMPOUNDING
PHARMACY, INC., et. al.,**

Defendants.

MEMORANDUM IN SUPPORT OF ALAUNUS PHARMACEUTICAL, LLC’S
MOTION TO DISMISS

The Defendant, Alaunus Pharmaceutical, LLC (“Alaunus”), by and through its counsel, hereby moves the Court to dismiss the amended complaint for failure to state a claim upon which relief may be granted pursuant to Fed. R. Civ. P. 12(b)(6).

I. INTRODUCTION

The amended complaint, which purports to be a class action products liability suit filed by Plaintiffs Raymond McDow (“McDow”) and Roseanne Brooks (“Brooks”), on behalf of themselves and all others similarly situated, asserts claims of negligence, negligent infliction of emotional distress, breach of express and implied warranties, battery, and constructive trust collectively against Alaunus, New England Compounding Pharmacy, Inc. (“NECC”), Ameridose, LLC (“Ameridose”), Medical Sales Management, Inc. (“MSM”), Gregory Conigliaro, Lisa Conigliaro Cadden, Douglas Conigliaro, Carla Conigliaro, Barry Cadden, and Gregory Chin. The claims arise out of alleged injuries suffered by McDow, Brooks, and the unnamed individuals in

the purported class from an injection of a steroid compound that Plaintiffs suspect were contaminated with a fungal agent. Plaintiffs assert that the steroid compound was manufactured or distributed by the Defendants. The complaint should be dismissed pursuant to Rule 12(b)(6) because it fails to state a plausible claim: (1) under any of the direct liability theories asserted against Alaunus since it does not plead enough facts to give rise to a reasonable inference that Alaunus manufactured or distributed any defective product into the stream of commerce, that Plaintiffs have suffered a legally compensable injury, that Plaintiffs' alleged injuries were caused by the defective product, and that the products consumed by Plaintiffs are fairly traceable to Alaunus; and, (2) for constructive trust since common ownership and management, without more, is not enough to hold Alaunus vicariously or jointly liable for any misconduct under an alter-ego, concerted action, aiding and abetting, or joint venture theory.

FACTUAL ALLEGATIONS IN THE FIRST AMENDED CLASS ACTION COMPLAINT

The first amended class action complaint alleges, in relevant part, that McDow, a resident of the state of Illinois, and Brooks, a resident of the state of New York, received at least one injection of Methylprednisone Acetate Product (MAP), a prescription steroidal medication which is compounded and provided in liquid form thereby requiring an injection for administration. Amended Compl. ¶¶ 61, 64. The complaint alleges that NECC voluntarily recalled lots of MAP injections that were contaminated with a fungal agent from the medical providers and facilities where they were distributed. *Id.* at 58. While Plaintiffs allege that contaminated MAP was distributed into the stream of commerce and that many people have become sick from fungal contamination, the amended complaint does not specify the date of their injections, the name and location of the medical provider of their injections, the lot number of the injections, or whether the product was brand name or generic. Nor does the complaint specify how the Plaintiffs learned that they may have been injected with contaminated MAP. Plaintiffs further concede that it is unknown whether all of the lots of MAP injections were contaminated. *Id.* at 59. Plaintiffs do not

claim that they have been diagnosed or treated for spinal meningitis. Rather, Plaintiffs claim that, as a result of their suspected exposure to contaminated MAP, they have suffered headaches, neck/back/chest pain, flu-like symptoms, and emotional distress, and that they have incurred medical expenses to monitor their conditions because they are at risk for developing fungal spinal meningitis. *Id.* at 62, 65.

Significantly, clinical administration of *non-contaminated* methylprednisolone acetate has been associated with various adverse reactions including, among other things, moderate to severe headaches, chest/neck/back pain, flu-like symptoms, and various neurological and psychiatric conditions. According to the warnings regarding infections on the FDA-approved labeling¹ for Depo-Medrol® brand-named methylprednisolone acetate:

"Persons who are on corticosteroids are more susceptible to infections than are healthy individuals . . . Infections with any pathogen (viral, fungal, protozoan, or helminthic), in any location of the body may be associated with the use of corticosteroids alone . . . These infections may be mild, but can be severe and at times fatal . . . Corticosteroids may exacerbate systemic fungal infections and therefore should not be used in the presence of such infections unless they are needed to control drug reactions . . . Latent disease may be activated or there may be an exacerbation of intercurrent infections due to pathogens. . . "²

In addition to the immunosuppressive warnings, the labeling further indicates that the use of injectable methylprednisolone acetate suspension may cause various adverse reactions including:

¹ This Court may consider the contents of the FDA-approved labeling for methylprednisolone acetate on a motion to dismiss under Rule 12(b)(6) without converting the motion to one for summary judgment because it is an official public record susceptible to judicial notice under Federal Rule of Evidence 201 and/or a document central to the plaintiffs' claim. *See Watterson v. Page*, 987 F.2d 1, 3 (1st Cir. 1998); *City of Sausalito v. O'Neill*, 386 F.3d 1186, 1223 n.2 (9th Cir. 2004) ("We may take judicial notice of a record of a state agency not subject to reasonable dispute"); *O'Toole v. Northrop Grumman Corp.*, 499 F.3d 1218, 1225 (10th Cir. 2007) ("It is not uncommon for courts to take judicial notice of factual information found on the world wide web"); *New Mexico ex rel. Richardson v. Bureau of Land Management*, 563 F.3d 683 (10th Cir. April 28, 2009) (No. 06-2352, 06-2353, 06-2354) (taking judicial notice of releases which were referred to on the websites of two federal agencies because it was not subject to reasonable factual dispute and is capable of determination using sources whose accuracy cannot reasonably be questioned).

² *See* U.S. FDA, MedWatch: The FDA Safety Information and Adverse Event Reporting Program, Safety Information - Depo-Medrol/S-085 Label (methylprednisolone acetate injectable suspension, USP), available at <http://www.accessdata.fda.gov/drugsatfda_docs/label/2009/011757s085s086lbl.pdf> (accessed Jan. 3, 2013).

cardiovascular diseases such as cardiac arrest, cardiac arrhythmias, and hypertension (all of which are associated with *chest pain*); musculoskeletal diseases and illnesses such as loss of muscle mass, muscle weakness, and osteoporosis (which is associated with *neck and back pain*); neurological and psychiatric disorders and symptoms such as increased intracranial pressure with papilledema (which is associated with moderate to severe *headaches*), as well as depression, emotional instability, mood swings, personality changes, and psychic disorders; and, other reactions such as appetite changes, nausea, increased sweating, and malaise (which are common *flu-like symptoms*).³

The factual allegations in the complaint regarding Alaunus are scant and are predominantly made upon information and belief. The complaint alleges that Alaunus' principal place of business is next door to that of NECC's, and that Alaunus holds itself out as a pharmaceutical developer and distributor for NECC and Ameridose. Compl. at ¶ 20. The complaint alleges that NECC, Alaunus and Ameridose share common officers and managers, including Gregory Conigliaro and Barry Cadden. *Id.* at 21. The complaint also alleges that NECC, Ameridose and Alaunus shared common facilities and resources for their businesses. *Id.* at 24. Based upon these allegations, Plaintiffs conclude that Alaunus, in conjunction with the other defendants, manufactured and distributed MAP into the stream of commerce which was contaminated with fungal agents which were capable of causing fungal meningitis. *Id.* at 4.

II. DISCUSSION

The complaint should be dismissed pursuant to Rule 12(b)(6) because it fails to allege sufficient factual allegations to show that McDow and Brooks have a plausible right to recovery against Alaunus under any of the theories of liability asserted in the complaint.

To survive a motion to dismiss under Fed.R.Civ.P. 12(b)(6), the factual allegations in a complaint must “possess enough heft” to set forth “a plausible entitlement to relief.” *Bell Atl.*

³ *See id.*

Corp. v. Twombly, 550 U.S. 544 (2007). To have facial plausibility, the complaint must contain “factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.” *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). The *Twombly-Iqbal* plausibility standard implicates a two-step analysis. *Grajales v. Puerto Rico Ports Authority*, 682 F.3d 40, 44 (2012), citing *Iqbal*, 556 U.S. at 678 - 679. First, “the court must separate the complaint’s factual allegations (which must be accepted as true) from its conclusory legal allegations (which need not be credited).” *Grajales*, 682 F.3d at 44, citing *Morales-Cruz v. Univ. of P.R.*, 676 F.3d 220, 224 (1st Cir.2012). Second, the court must determine whether the factual content permits “the reasonable inference that the defendant is liable for the misconduct alleged.” *Grajales*, 682 F.3d at 44 (internal quotation marks omitted), citing *Sepúlveda-Villarini v. Dep’t of Educ. of P.R.*, 628 F.3d 25, 29 (1st Cir.2010) (Souter, J.) (“The make-or-break standard ... is that the combined allegations, taken as true, must state a plausible, not a merely conceivable, case for relief”). “If the factual allegations in the complaint are too meager, vague, or conclusory to remove the possibility of relief from the realm of mere conjecture, the complaint is open to dismissal.” *Plumbers’ Union Local No. 12 Pension Fund v. Nomura Asset Acceptance Corp.*, 632 F.3d 762, 771 (1st Cir. 2011).

1. Other than the allegations of common control and management, as well as the vicinity of Alaunus’ facility to NECC’s facility, all of the other allegations concerning Alaunus should be disregarded by the Court.

On a motion to dismiss, “a plaintiff’s obligation to provide the ‘grounds’ of [her] ‘entitle[ment] to relief’ requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do.” *Twombly*, 127 S.Ct. at 1965. Naked assertions devoid of further factual enhancement need not be accepted. *Maldonado v. Fontanes*, 568 F.3d 263, 266 (1st Cir. 2009).⁴ “Conclusions” only become “facts” for pleading purposes when “conclusions are

⁴ See also *Barrington Cove Ltd. Partnership v. Rhode Island Housing and Mortg. Finance Corp.*, 246 F.3d 1 (1st Cir.2001) (ruling that the court should not credit “conclusory assertions, subjective characterizations, or outright vituperation”); *Aulson v. Blanchard*, 83 F.3d 1, 3 (1st Cir. 1996) (stating that

logically compelled, or at least supported, by the stated facts," as well as the reasonable inferences drawn therefrom. *The Dartmouth Review v. Dartmouth College*, 889 F.2d 13, 16 (1st Cir. 1989).

While the *Twombly-Iqbal* plausibility standard does not prevent a plaintiff from pleading facts alleged 'upon information and belief' where the facts are peculiarly within the possession and control of the defendant, *see, e.g., Boykin v. KeyCorp.*, 521 F.3d 202, 215 (2d Cir. 2008), or where the belief is based on factual information that makes the inference of culpability plausible, *see Iqbal*, 129 S. Ct. at 1949," a plaintiff does not make a showing of a plausible entitlement to relief simply by reciting a formula of facts "upon information and belief" regarding each of the elements of a cause of action. When a plaintiff alleges a fact "upon information and belief," the assertion signifies that the "allegations are based on secondhand information that [the asserting party] believes to be true." *Pirelli Armstrong Tire Corp. Retiree Med.Benefits Trust v. Walgreen Co.*, 631 F.3d 436, 442 (7th Cir. 2011) (quoting Black's Law Dictionary 783 (7th ed. 1999); *Zuk v. E. Pa. Psychiatric Inst. of the Med.Coll. of Pa.*, 103 F.3d 294, 299 (3d Cir. 1996). In the absence of factual allegations of secondhand information that the plaintiff believes to be true which logically compels or supports an allegation that is made "upon information and belief," such an allegation is merely a conclusory assertion that should not be deemed to be true by the court on a motion to dismiss. *See Twombly*, 127 S. Ct. at 1962-1963, and 1970 (affirming district court's ruling that plaintiffs' allegation, which was made upon information and belief, that the defendants entered into a contract, combination or conspiracy to prevent competitive entry in markets, was merely a conclusory assertion because the factual allegations of parallel conduct, as opposed to independent allegations of actual agreement among the defendants, did not compel or support the conclusion that the defendants entered into a conspiracy agreement).

While the complaint asserts that Alaunus was jointly involved in the manufacturing, mixing, compounding, selling, and distributing of contaminated MAP into the stream of

the court is not obligated "to swallow the plaintiff's invective hook, line, and sinker; bald assertions, unsupportable conclusions, periphrastic circumlocutions, and the like need not be credited").

commerce, *Compl.* ¶ 4, there are insufficient factual allegations to support that conclusion.

Ostensibly, Plaintiffs base this conclusion on the allegations that Alaunus has a principal place of business next door to that of NECC's, *id.* at ¶ 20, that NECC, Alaunus and Ameridose share common officers and managers, *id.* at 21, that NECC, Ameridose and Alaunus shared common facilities and resources for their businesses, *id.* at 24, and that Alaunus holds itself out as a pharmaceutical developer and distributor for NECC and Ameridose, *id.* at ¶ 20. However, the complaint does not plead any facts which support the assertion that Alaunus shared common facilities and resources for their business or the assertion that Alaunus held itself out as a developer and distributor of products manufactured by NECC or Ameridose. Even assuming for the purposes of a motion to dismiss that there was common ownership and management between Alaunus, NECC, and Ameridose, such facts do not logically compel or even support an inference that Alaunus was jointly involved in the manufacture and distribution of MAP and that Plaintiffs received injections of contaminated product. Consequently, the statements or suggestions in the complaint that Alaunus was engaged in the business of manufacturing and distributing MAP, that Alaunus distributed contaminated MAP into interstate commerce, and that Plaintiffs received an injection of contaminated MAP that was distributed by Alaunus, are all conclusory assertions masquerading as factual allegations which should not be taken as true on a motion to dismiss. *See Twombly*, 127 S. Ct. at 1962-1963, and 1970; *The Dartmouth Review*, 889 F.2d at 16.

2. **The fact that Alaunus shared the same registered agent for service of process and the same officers and managers as NECC and Ameridose does not permit a reasonable inference that Alaunus is liable under any of the theories of liability asserted in the complaint.**

The complaint predicates the Plaintiffs' manufacturing defect claim under theories of negligence, negligent infliction of emotional distress, breach of express and implied warranties, and battery. Putting aside the conclusory assertions in the complaint, the pleading fails to state a plausible right to recovery under any of those theories of recovery.

a. Negligence

To prove a negligent manufacturing claim, a plaintiff must show that the defect existed at the time the product left the manufacturer, *Smith v. Ariens Co.*, 375 Mass. 620, 626 (1978), that she suffered an injury, that her injury was caused by the defective product, and that his or her injury can be traced to that specific manufacturer, *Mathers v. Midland-Ross Corp.*, 403 Mass. 688 (1989); *Carrier v. Riddell, Inc.*, 721 F.2d 867, 869-870 (1st Cir.1983) (applying Massachusetts law). Plaintiffs' complaint falls short of satisfying these elements.

- (i) The amended complaint does not sufficiently allege the existence of a defect, causation, or that Plaintiffs' purported injuries are fairly traceable to Alaunus.

The complaint does not specify the date of the Plaintiffs' injections, the name and location of the medical provider of their injections, the lot number of the injections, the name of the manufacturer listed on the injection vials, or whether the product was brand name or generic. Plaintiff's failure to specify that information is particularly problematic because they concede that it is unknown whether all of the lots of MAP injections were contaminated. Plaintiffs do not claim to have been diagnosed with any disease as a result of receiving any MAP injection and the headaches, muscle pains, and flu-like symptoms that they claim to suffer from are also known to be reactions to *non-contaminated* methylprednisolone acetate according to the FDA-approved labeling for the drug. Given that the complaint does not plead facts connecting the supposedly contaminated products that were distributed in interstate commerce with the MAP injections received by the Plaintiffs, the assertion in the complaint that the Plaintiffs' injections were contaminated with a fungal agent, that the MAP injection caused them injuries, and that they suffered an actual injury from such defect is based on nothing more than pure conjecture and speculation. For these reasons, the complaint does not plead a plausible negligence claim against Alaunus. *See Patterson v. Novartis Pharmaceuticals Corp.*, 451 Fed. Appx. 495 (6th Cir. Aug. 23, 2011) (holding that district court properly granted defendant's motion to dismiss under *Twombly*-

Iqbal because Massachusetts law requires that a plaintiff suing a manufacturer in a product-liability action be able to prove that his or her injury can be traced to that specific manufacturer and the factual allegations in the complaint only permitted the Court to infer the possibility that the plaintiff received infusions of the name-brand drug, Aredia, manufactured by Novartis, as opposed to the generic equivalent manufactured by some other manufacturer).⁵

(ii) The Plaintiffs have not alleged a legally sufficient injury

It is axiomatic that a plaintiff in a negligence suit must prove that he has suffered an actual injury or damages. *Cannon v. Sears, Roebuck & Co.*, 374 Mass. 739, 742 (1978) ("a negligence action may not be maintained unless one has suffered injury or damage"). The headaches, muscle pains, and flu-like symptoms that the Plaintiffs claim to suffer from are wholly consistent with *side effects* associated with the clinical use of *non-contaminated* methylprednisolone acetate injections. If indeed the Plaintiffs are suffering from mere side effects of non-contaminated MAP, those are not actual, present injuries for which recovery may be had under a manufacturing defect or failure to warn theory.⁶ Given that the Plaintiffs do not claim that they been diagnosed with spinal

⁵ See also *In re Fosamax Products Liability Litigation*, 2010 WL 1654156 (S.D.N.Y. April 9, 2010) (dismissing all product liability claims on grounds that plaintiff's complaint failed to allege sufficient facts to identify manufacturer of product observing that statement in the complaint that "Defendants, either directly or through [their] agents, apparent agents, servants, or employees, at all relevant times, designed, tested, developed, manufactured, labeled, marketed, distributed and sold Fosamax and Boniva" was conclusory since the complaint did not provide any specifics to support such a conclusion); *Henderson v. Sun Pharmaceuticals Industries, Ltd.*, 809 F. Supp.2d 1373 (N.D. Ga. Aug. 22, 2011) (all claims dismissed under *Twombly-Iqbal* due, in relevant part, to failure to allege sufficient factual allegations to identify the defendant that manufactured the product); *Singleton v. Eli Lilly Co.*, 2011 WL 2621067 (E.D. Cal. June 29, 2011) (all claims in prescription drug case dismissed under *Twombly-Iqbal* due to failure to allege sufficient factual allegations to identify the product's manufacturer).

⁶ Any duty to warn was owed by the manufacturer to the physician as a learned intermediary, not to the Plaintiff patients, because MAP injections are administered by physicians to their patients. See *Knowlton v. Deseret Medical, Inc.*, 930 F.2d 116, 120 n. 2 (1st Cir.1991) ("it is generally accepted that in a case involving medical products prescribed or used by a physician or trained medical personnel, the warning runs to the physician not the patient"). Given that the product labeling and other medical literature which is readily available to the physician warns that a patient may suffer from adverse reactions including headaches, back/neck/chest pains, and flu-like symptoms, the manufacturer of the MAP injections is shielded from liability under the learned intermediary doctrine since it had a reasonable "justified reliance upon ... a middleman," see *MacDonald v. Ortho Pharmaceuticals Corp.*, 394 Mass. 131, 136 (1985), as well as the sophisticated user doctrine since "the end user [the physician] knows or reasonably should know of a product's dangers," see *Hoffman v. Houghton Chemical Corp.*, 434 Mass. 624, 630 (2001). See

meningitis or any other disease as a result of their MAP injections and the complaint does not plead facts connecting the allegedly contaminated MAP injections that were distributed into the stream of commerce with the injections received by the Plaintiffs, the amended complaint does not plead anything more than a *possibility* that they might contract some disease in the future and therefore must be dismissed for failure to assert a plausible injury claim. *Watkins v. Omni Life Science Inc.*, 2010 WL 809820, slip op. (D. Mass. March 9, 2010) (fear of future harm from potential failure of hip implant is not sufficient injury).⁷

Nor is the Plaintiffs' alleged emotional distress enough to show that they have suffered an actual injury under a negligence theory. Where a plaintiff seeks emotional distress damages in a negligence action, the plaintiff may not recover emotional distress damages unless such emotional distress *stems* from a *physical injury* inflicted by the defendant's negligent conduct. *DiGiovanni v. Latimer*, 390 Mass. 265 (1983). *See Barney v. Magen*, 241 Mass. 268, 273 (1922) (allowing recovery for mental suffering "connected with and growing out of the physical injury"); *Bullard v. Central Vermont Ry.*, 565 F.2d 193, 197 (1st Cir.1977) (recovery allowed for "necessary or natural consequence of the physical injury" but not for grief, sorrow or mourning).⁸ That Plaintiffs

also Chamian v. Sharplan Lasers, Inc., 18 Mass.L.Rptr. 308, 2004 WL 2341569 (Mass. Super. 2004) (manufacturer shielded from liability under learned intermediary and sophisticated user doctrines in case where plaintiff claimed that she suffered severe facial scarring and skin discoloration after undergoing laser cosmetic surgery because the users of the laser equipment, licensed physicians, were highly trained and experienced medical professionals who were aware of the risk of burning and scarring from overexposure to the laser treatment).

⁷ *See also Mink v University of Chicago*, 460 F. Supp. 713 (N.D. Ill. Mar. 17, 1978) (increased risk and/or fear of future serious disease from exposure to DES is not sufficient injury); *Aberbach v. Biomedical Tissue Services, Ltd.*, 854 N.Y.S.2d 143 (N.Y. App. Div. Feb. 26, 2008) ("potential" for infection by bone paste is not sufficient injury); *Plummer v. Abbott Laboratories*, 568 F. Supp. 920 (D.R.I. July 1, 1983) (same); *Hagepanos v. Shiley, Inc.*, 846 F.2d 71 (unpublished), 1988 WL 35752 (4th Cir. Apr. 18, 1988) (applying Maryland law) (increased risk/fear of heart valve failure is not sufficient injury to recover under theories of negligence, strict liability, express warranty, and implied warranty); *Burk v. Sage Products, Inc.*, 747 F. Supp. 285 (E.D. Pa. Sept. 27, 1990) (fear of AIDS from needlestick was not sufficient injury, without proof of actual exposure).

⁸ The courts have distinguished between "parasitic" claims of emotional distress which stem from physical injuries and free-standing negligent and intentional infliction of emotional distress claims. *See*

allegedly suffer from emotional distress is of no avail to them under a negligence theory because the complaint does not allege that their purported emotional distress stems from any *physical injury* caused by the injections for the reasons previously discussed. *See Anderson v. W.R. Grace & Co.*, 628 F.Supp. 1219, 1228-1229 (D. Mass. 1986) (concluding that plaintiffs that had contracted leukemia could recover for emotional distress stemming from physical harm to plaintiffs' immune systems by exposure to contaminated water, while non-leukemic plaintiffs who alleged that they suffered emotional distress “as a result of the knowledge that they ... have consumed hazardous chemicals” were not entitled to any recovery because the emotional distress did not stem from any physical harm caused by the defendants).

Moreover, the Plaintiffs are not entitled to any recovery for the medical costs of monitoring their condition to determine if they develop spinal meningitis or other disease. Under Illinois law, any medical monitoring claim by McDow fails because Illinois does not recognize medical monitoring claims as a matter of law. *See Lewis v. Lead Industries Ass’n, Inc.*, 793 N.E.2d 869, 877 (Ill. App. 2003) (declining to permit a medical monitoring remedy as an independent equitable claim); *Guillory v. American Tobacco Co.*, 2001 WL 290603, at *7 (N.D. Ill. 2001) (rejecting medical monitoring). Further, the complaint fails to state a claim for medical monitoring as to Brooks under New York and Massachusetts law because the complaint does not plausibly show that Brooks has, in fact, been exposed to contaminated MAP, and it does not plead facts showing that she has any clinically demonstrable presence of fungal contamination, any physical manifestations of such contamination, or subcellular changes indicating that she might develop meningitis in the future. *See Abusio v. Consolidated Edison Co.*, 656 N.Y.S.2d 371, 372 (N.Y. A.D. 1997) (in order to maintain a cause of action for future medical monitoring costs following exposure to a toxic substance, a plaintiff must not only establish that he was in fact exposed to the disease-causing agent, but also that there is a “clinically demonstrable presence” of contaminants

Payton v. Abbott Labs, 386 Mass. 540 (1982). Plaintiffs' claim for negligent infliction of emotional distress is discussed in the next section.

in plaintiff's body or some other physical manifestation of contamination from toxic substance); *Donovan v. Philip Morris USA, Inc.*, 455 Mass. 215, 224, 226 (2009) (in order to state claim for medical monitoring under Massachusetts law, a plaintiff must prove, among other things, that the defendant's negligence caused the plaintiff to become exposed to a hazardous substance that produced, at least, subcellular changes that substantially increased the risk of serious disease, illness, or injury); *Miranda v. Dacruz*, 2009 WL 3515196 (R.I. Super. 2009) (Trial Order) (holding that the plaintiff was not entitled to medical monitoring damages because, "unlike the *Donovan* plaintiffs whose lung tissues exhibited changes that warned of potential cancers, [plaintiff's] kidneys, heart, and nerves do not present any physiological changes indicative of future harm").

b. Negligent Infliction of Emotional Distress

Similarly, Plaintiffs have failed to state a claim for negligent infliction of emotional distress. In order to recover for negligently inflicted emotional distress in Massachusetts, a plaintiff must prove (1) that the defendant was negligent, (2) that the plaintiff suffered from emotional distress, (3) that the emotional distress was caused by the defendant's negligence, (4) physical harm manifested by objective symptomatology, and (5) that a reasonable person would have suffered emotional distress under the circumstances of the case. *Payton v. Abbott Labs*, 386 Mass. 540 (1982). In addition to the lack of allegations showing that Alalunus was negligent or that its alleged negligence caused the Plaintiffs' purported injuries, Plaintiffs have failed to satisfy the physical harm requirement because the headaches, muscle pains, and flu-like symptoms - the only objective symptomatology mentioned in the complaint - stem from the injections and are not symptoms of any emotional distress. *See Payton*, 386 Mass. at 555 ("in order for any of these plaintiffs to recover for negligently inflicted emotional distress, she must allege and prove she suffered physical harm as a result of the conduct which caused the

emotional distress”).⁹

c. Breach of Express Warranty

The express warranty claim should be dismissed for failure to state a claim for relief because the complaint pleads insufficient facts to show that an express warranty was created by Alaunus, that Plaintiffs relied on any such express warranty, and that Mr. Martin suffered an injury as a result of Alaunus' breach of such a warranty.

It is well-settled that in order to recover for breach of an express warranty under Section 2-313 of the UCC,¹⁰ the plaintiff must show an affirmation of fact or promise made by the seller to the buyer and that the affirmation of fact or promise was made under such circumstances as to warrant the inference that it related to the goods. *O'Connell v. Kennedy*, 328 Mass. 90 (1951); *Leavitt v. Fiberloid Co.*, 196 Mass. 440, 445 (1907). The Plaintiffs' complaint baldly asserts that “included with the steroid injection at the time of purchase were express and implied warranties made by Defendants affirming that the product was dependable, reliable, free from defects of merchantable quality, of fair use and quality, sterile, and fit for its intended purpose.” The only statement in the complaint that remotely pertains to the alleged express warranty is the assertion in paragraph 53 of the amended complaint that “Defendants falsely and fraudulently *kept* relevant information from potential steroid users and their doctors and clinics, and minimized user and prescriber concern regarding the safety of these drugs.” Given that the complaint does not plead

⁹ See also *Poole v. Alpha Therapeutic Corp.*, 698 F. Supp. 1367, 1371 (N.D. Ill. 1988) (“courts have consistently refused to allow recovery for mental or emotional distress in the absence of a physical injury or illness”); *In re Rezulin Products Liability Litigation*, 361 F. Supp.2d 268, 278 (S.D.N.Y. 2005) (where there was no evidence that plaintiffs’ alleged injuries manifested any clinically observable detriment and any future consequences from plaintiffs’ alleged injuries were purely speculative, plaintiffs’ alleged mitochondrial damage was therefore not a manifest injury); *Nesom v. Tri Hawk International*, 985 F.2d 208, 211 (5th Cir. 1993) (“allow[ing] someone to recover merely because he fears that he may have been exposed to a dangerous substance goes too far”).

¹⁰ In Massachusetts, the creation of express warranties is governed by M.G.L. c. 106 § 2–313, which provides, in relevant part, that (a) any affirmation of fact or promise made by the seller to the buyer which relates to the goods and becomes part of the basis of the bargain creates an express warranty that the goods shall conform to the affirmation or promise; and, (b) any description of the goods which is made part of the basis of the bargain creates an express warranty that the goods shall conform to the description.

any facts, as opposed to conclusory assertions, regarding the specific affirmation of fact or promise that was made by Alaunus to Mr. Martin or otherwise identify any of the specific materials which were supposedly sent by Alaunus to the Plaintiffs, the express warranty claim should be dismissed for failure to state a claim pursuant to *Twombly* and *Iqbal*. See *Johnson v. Brown & Williamson Tobacco Corp.*, 122 F. Supp. 2d 194, 206 (D. Mass. 2000) (dismissing express warranty claim for failure to sufficiently plead facts showing the existence of an express warranty where plaintiff claimed that the defendant extended an express warranty to the decedent through its "advertising, marketing and other efforts," but offered no specific affirmation of fact or promise, nor any particular description, sample or model that might give rise to such a warranty).¹¹

It is also well-settled that the affirmation of fact or promise by the seller must have become part of the "basis of the bargain" in order for the buyer to recover for breach of an express warranty. *O'Connell v. Kennedy*, 328 Mass. 90 (1951); *Leavitt v. Fiberloid Co.*, 196 Mass. 440, 445 (1907). Although there is a split of authority on this issue in various jurisdictions, the district court and superior court in Massachusetts has consistently held that an express warranty only becomes part of the "basis of the bargain" where the buyer relied on the seller's affirmation of fact or promise in making the purchase or using the product. See *Stuto v. Corning Glass Works*, Prod.Liab.Rep. (CCH) P 12,585, 1990 WL 105615 (D. Mass. 1990) (Wolf, C.J.); *DiRamio v. Crosby*, Civil No. 03-4872 (Mass. Super. Ct. July 18, 2007) (Botsford, J.); *Fahey v. R.J. Reynolds Tobacco Co.*, Civil No 92-7221, 1995 WL 809837, (Mass. Super. Ct. 1995) (Borenstein, J.); Hiller

¹¹ See also *Varney v. R.J. Reynolds Tobacco Co.*, 118 F.Supp.2d 63, 70 (D.Mass.2000) (dismissal of express warranty claim appropriate where plaintiff at no point pleads "the existence of anything remotely resembling an express warranty"); *Heisner v. Genzyme Corp.*, 2008 WL 2940811 (N.D. Ill. July 25, 2008) (express warranty claim in medical device case dismissed under *Twombly* due to plaintiff's failure to specify the language that constituted the warranty since complaint did not allege any particular affirmation, promise, description, or sample that formed part of the basis of his bargain with defendant); *Simmons v. Stryker Corp.*, (D. N.J. 2008) (express warranty claim dismissed under *Twombly* due to plaintiff's failure to specify the language that constituted the warranty and the source material containing the alleged warranty); *Wendell v. Johnson & Johnson*, 2010 WL 271423 (N.D. Cal. Jan. 20, 2010) (where complaint alleged that defendants "warranted" that the products were "safe, effective, fit and proper for their intended use," and that the products "were not safe and were unfit" for their intended uses," court dismissed express and implied warranty claims because plaintiffs failed to allege the contents of any specific warranty or the breach thereof).

v. DaimlerChrysler Corp., 23 Mass.L.Rptr. 202, 2007 WL 3260199 (Mass. Super. 2007) (Henry, J.); *Carter v. Scubapro*, 2011 WL 3107334 (D. Mass. 2011) (Gertner, J.) (order adopting and affirming report and recommendation of magistrate). Whereas the complaint fails to plead any facts showing that Plaintiff relied on any affirmation of fact or promise made by Alaunus and that the Plaintiffs' injuries were caused by Alaunus, the complaint fails to state a plausible claim for breach of express warranty. *See Stuto, supra*, 1990 WL 105615, * 5 (granting summary judgment to defendant on express warranty claim because some minimum of reliance is a required element of a breach of express warranty claim in Massachusetts and the record clearly demonstrated that plaintiff could not have relied on the express warranty that she claimed were created in defendant's advertisements);¹² *Pennsylvania Employees Benefit Trust Fund v. Astrazeneca Pharmaceuticals LP*, 2009 WL 2231686 (M.D. Fla. July 20, 2009) (express warranty claims dismissed under *Twombly-Iqbal* due to failure, in relevant part, to plead any facts in drug case showing proximate cause between breach of warranty and plaintiffs' alleged injuries).

d. Breach of Implied Warranty of Merchantability

Under M.G.L. c. 106, § 2-314(2)(c), a seller impliedly warrants that a product is "fit for the ordinary purposes for which such goods are used." To establish a breach of implied warranty of merchantability claim, the plaintiff must allege and prove that: (1) the defendant was a merchant, *Ferragamo v. MBTA*, 395 Mass. 581, 586 (1985); (2) the product was sold or leased, *Mason v. Gen. Motors Corp.*, 397 Mass. 183, 189 (1986); (3) the plaintiff's use of the product was foreseeable, *Allen v. Chance Mfg. Co.*, 398 Mass. 32, 34 (1986); (4) the product was defective,

¹² *See also Carter, supra*, 2011 WL 3107334, * 4 (granting summary judgment to defendant on express warranty claim because plaintiff offered no evidence whatsoever of reliance upon or even knowledge of any express warranty); *Hagenbuch v. Snap-On Tools Corp.*, 339 F.Supp. 676, 10 U.C.C. Rep. Serv. 1005 (D.N.H. 1972) (no warranty created in a sale of a hammer since the buyer did not rely on the statements contained in the seller's catalogue); *Thomas v. Amway Corp.*, 488 A.2d 716, 40 U.C.C. Rep. Serv. 836 (R.I. 1985) (no express warranty in a sale of liquid soap since the buyer did not rely on the statements on the label); *Horsmon v. Zimmer Holdings, Inc.*, 2011 WL 5509420 (W.D. Pa. Nov. 10, 2011) (express warranty claim dismissed under *Twombly-Iqbal* due to failure to plead the specifics regarding the alleged warranty or how it became part of the basis of the bargain); *Deese v. Immunex Corp.*, 2012 WL 463722 (S.D. Miss. Feb. 13, 2012) (express warranty claims in prescription drug case dismissed for failure to state a claim under *Twombly-Iqbal* due to failure to plead the warranty or how it became part of the basis of the bargain).

Correia v. Firestone Tire & Rubber Co., 388 Mass. 342, 355 (1983); and, (5) the defect was a proximate cause of the plaintiff's injury, *Swartz v. Gen. Motors Corp.*, 375 Mass. 628, 633 (1978), *Barry v. Stop & Shop Co.*, 24 Mass. App. Ct. 224 (1987).

The complaint fails to state a claim for breach of implied warranty of merchantability. The claim is not plausible because, other than conclusory assertions, the complaint does not allege sufficient facts to show that Alaunus was a merchant of MAP who deals in goods of the kind or otherwise held itself out as having knowledge or skill peculiar to the goods involved in the transaction. *See Ferragamo v. MBTA*, 395 Mass. 581, 586 (1985). Additionally, the breach of implied warranty of merchantability claim is not plausible for the same reason as the negligence claim: there are no factual allegations beyond conclusory assertions that Alaunus distributed any contaminated MAP into the stream of commerce or that Mr. Martin's alleged injuries were caused by contaminated MAP that was manufactured or distributed by Alaunus.¹³

e. Implied Warranty of Fitness for a Particular Purpose

To state a claim for breach of implied warranty of fitness for a particular purpose under M.G.L. c. 106, § 2-315, the plaintiff must show that 1) the seller had reason to know of the particular purpose for which the buyer required the goods, 2) the seller had reason to know of the buyer's reliance on the seller's skill or judgment in selecting or furnishing suitable goods, and 3) the buyer relied in fact. *Fernandes v. Union Bookbinding Co.*, 400 Mass. 27, 34 (1987). Whereas the complaint fails to assert any facts showing that the medical providers were going to use the

¹³ See footnote 5 above. *See also In re Fosamax Products Liability Litigation*, 2010 WL 1654156 (S.D.N.Y. April 9, 2010) (all product liability claims in drug case dismissed under *Twombly-Iqbal* due to failure to plead facts concerning product identification); *Johnson v. Moog, Inc.*, 2011 WL 719600 (E.D. Tex. Feb. 22, 2011) (all claims in medical device case dismissed under *Twombly-Iqbal* because the pleading asserted only that unknown "defendants" committed actions and failed to state sufficient facts to identify defective product); *Mitchell v. Proctor & Gamble*, 2010 WL 728222 (S.D. Ohio March 1, 2010) (all product liability claims in drug case dismissed under *Twombly-Iqbal* due to failure to plead causation); *Adams v. I-Flow Corp.*, No. CV09-09550, 2010 WL 1339948, at *3 (C.D.Cal. Mar.30, 2010) (dismissing products liability claims because complaint did not allege that any particular plaintiff was administered a particular drug through a particular pain pump that was manufactured by a particular defendant; plaintiffs plead nothing more than the sheer possibility that any particular defendant might have manufactured the product that allegedly injured each plaintiff).

MAP injections in any manner other than its ordinary purpose in medicine, Plaintiff's claim of breach of implied warranty of fitness must be dismissed as a matter of law. *See Hannon v. Original Gunite Aquatech Pools, Inc.*, 385 Mass. 813, 821 (1982) (where there was no evidence that the buyer was going to use the pool in question for any purpose other than for what a pool is normally used, no particular purpose existed as required for liability under § 2-315).¹⁴ Moreover, the claim for breach of implied warranty of fitness for a particular purpose should be dismissed for failure to state a claim for relief for the same reasons as the negligence and breach of implied warranty of merchantability claims because there are no factual allegations beyond conclusory assertions that Alaunus distributed any contaminated MAP into the stream of commerce or that Mr. Martin's alleged injuries were caused by Alaunus' product.¹⁵

f. Battery

To prevail on a case of battery, a plaintiff must prove that the defendant had intentional, unpermitted contact with another person for the purpose of accomplishing a harmful or offensive contact or with knowledge that to a substantial certainty such a result will ensue. *Waters v. Blackshear*, 412 Mass. 589, 590–591 (1992). As the District Court (Wolf, D.J.) stated in *Moore v. Eli Lilly and Co.*, 626 F.Supp. 365 (D. Mass. 1986), in the medical context, a cause of action for battery may only be maintained where there is a *lack of any consent* by the patient to the treatment, *In the Matter of Spring*, 380 Mass. 629, 638 (1980), *Mink v. University of Chicago*, 460 F.Supp. 713, 717 (N.D.Ill.1978), while he must rely on a negligence action alleging a *lack of informed consent* if the patient was aware that he was given some form of drug but claims that he was not

¹⁴ See also *International Petroleum Servs., Inc. v. S & N Well Serv., Inc.*, 230 Kan. 452, 455–457 (1982) (ruling that when goods are acquired for the ordinary purposes for which such goods are generally used, no implied warranty of fitness for a particular purpose arises); *Grinage v. Mylan Pharmaceuticals, Inc.*, 840 F.Supp.2d 862, 2011 WL 6951962 (D. Md. Dec. 30, 2011) (implied warranty of fitness for particular purpose claim dismissed under *Twombly-Iqbal* due to failure to plead any facts showing that plaintiff's husband had any particular purpose that differed from that of other consumers of the prescription drug or that manufacturer had any knowledge of a particular purpose).

¹⁵ See footnotes 5 and 9 above.

informed about a medication's inherent dangers, *Mink*, 460 F.Supp. at 717, *Halley v. Birbiglia*, 390 Mass. 540 (1983). The complaint fails to state a plausible claim for battery not only because it does not plead facts to show that Plaintiff's alleged injuries are fairly traceable to Alaunus, but also because it fails to allege facts which, if proven, would establish a *lack of consent*, rather than a *lack of informed consent* since Plaintiffs do not allege that they did not consent to the receipt of any MAP injection. *See Moore*, 626 F.Supp. at 368 (ruling, in pharmaceutical drug case, that plaintiffs' battery claim against manufacturer was futile where complaint did not allege that lead plaintiff did not consent to take drug at issue).

g. Constructive Trust (Concerted Action, Aiding and Abetting, Joint Venture, and Alter-Ego Liability)

A constructive trust may be said to be a device employed in equity, in the absence of any intention of the parties to create a trust, in order to avoid the unjust enrichment of one party at the expense of the other where the legal title to the property was obtained by fraud or in violation of a fiduciary relation or where information confidentially given or acquired was used to the advantage of the recipient at the expense of the one who disclosed the information. *Barry v. Covich*, 332 Mass. 338 , 342 (1955). Absent fraud, breach of a fiduciary duty or other misconduct, the courts shall not impose a constructive trust. *Id.* The amended complaint fails to state a claim for constructive trust not only because the equitable doctrine is only applicable to prevent unjust enrichment of title to real property (no property was given to the Defendants, let alone real estate), but also because there is no fraud, breach of a fiduciary duty or other misconduct by Alaunus.

Ostensibly, Plaintiffs' claim that Alaunus is vicariously liable for NECC's or Ameridose's conduct based upon an alter-ego theory.¹⁶ In Massachusetts, alter ego liability requires showing of

¹⁶ Paragraph 34 of the amended complaint asserts that "Plaintiffs are informed and believe and herein allege that at all times herein mentioned, there exists and/or existed a unity of interest in ownership between NECC, Ameridose, MSM as well as Alaunus, such that any individuality and separateness between them has ceased, and each such entity is the *alter ego* of each other entity. Adherence to the fiction of the separate existence of each such Defendant as an entity distinct from each other would permit an abuse of the corporate privilege, *sanction fraud*, and promote injustice."

“active and direct participation by the representatives of one corporation, apparently exercising some form of pervasive control, in the activities of another and there is some fraudulent or injurious consequence of the intercorporate relationship” or “a confused intermingling of activity of two or more corporations engaged in a common enterprise with substantial disregard of the separate nature of the corporate entities, or serious ambiguity about the manner and capacity in which the various corporations and their respective representatives are acting.” *My Bread Baking Co. v. Cumberland Farms, Inc.*, 353 Mass. 614 (1968). Disregarding the bald, formulaic assertion of the elements of alter-ego liability in the complaint, the only fairly plead allegation regarding Alaunus is that there was common control and management of Alaunus, Ameridose, and NECC. Even assuming those factual allegations to be true for the purposes of a 12(b)(6) motion, such facts are not enough to make out a plausible claim for alter-ego liability. *See United States v. Bestfoods*, 524 U.S. 51, 69 (1998) (overlap in directors or officers among affiliated corporate entities is not unusual, and is widely held to be insufficient to establish alter ego liability alone); *Resolution Trust Corp. v. Driscoll*, 985 F.2d 44, 48 (1st Cir. 1993) (affirming dismissal of claims against corporate defendant because naked assertion of alter ego liability was not supported by sufficient factual allegations).¹⁷

Nor does the complaint state a claim for relief under any theory of joint liability. Common control and management is insufficient, as a matter of law, for the purpose of showing a plausible claim for concerted action liability, *see Santiago v. Sherwin Williams Co.*, 3 F. 3d 546 (1st Circ. 1993) (affirming dismissal of concerted action claim because, even if there was a common design or plan to market and sell paint notwithstanding medical evidence that lead presented significant risk to children, there was no showing that such marketing plan had any role in causing lead paint to be applied to the walls of her childhood home or otherwise caused injury to plaintiff), aiding and

¹⁷ *See also Akzona, Inc. v. E.I. Du Pont de Nemours & Co.*, 607 F. Supp. 227, 237 (D. Del. 1984) (holding that overlapping directors was insufficient to pierce veil); *Scott-Douglas Corp. v. Greyhound Corp.*, 304 A.2d 309, 314 (Del. Super. Ct. 1973) (same).

abetting liability, *see Kyte v. Philip Morris, Inc.*, 408 Mass. 162, 167-168 (1990) (no aiding and abetting liability where there was no proof that the defendant cigarette manufacturer gave substantial assistance to a store's sale of cigarettes to minors or knew that the store's conduct constituted a breach of duty to minors purchasing cigarettes), or joint venture liability, *see Payton v. Abbott Labs*, 512 F. Supp. 1031 (D. Mass. 1981) (elements of joint venture liability include an agreement among the parties to associate themselves in a business activity, the sharing in the profits and losses of the venture, joint control of the objectives of the undertaking and of the means of achieving those objectives, and a contribution to the assets of the venture).

III. CONCLUSION

In sum, the complaint fails to state a claim under any of the direct liability theories asserted against Alaunus because it does not plead enough facts to give rise to plausible inference that Alaunus manufactured or distributed contaminated MAP into the stream of commerce, that Plaintiffs have suffered a legally compensable injury, that Plaintiffs' alleged injuries were caused by contaminated MAP, and that Plaintiffs' MAP injections are fairly traceable to Alaunus. Additionally, the amended complaint does not assert a plausible claim for vicarious or joint liability because common ownership and management, without more, is not enough to make out a claim for alter-ego, concerted action, aiding and abetting, or joint venture liability. For these reasons, Plaintiffs are not entitled to conduct any discovery to cure the defects in their pleading¹⁸ and the Court should dismiss the complaint in its entirety, or at the very least as to Alaunus, pursuant to Fed.R.Civ.P. 12(b)(6).

¹⁸ *See Twombly*, 127 S. Ct. at 1966 (where discovery would be massive since the plaintiffs represent a putative class of at least 90 percent of all subscribers to local telephone or high-speed Internet service in the continental United States in an action against America's largest telecommunications firms, Supreme Court rejected the arguments that a plaintiff should be permitted to proceed with discovery and that case management techniques may be used by defendants to weed out baseless claims in an anti-trust case ruling that one of the main goals of the plausibility standard is the avoidance of unnecessary discovery); *Dura Pharmaceuticals, Inc. v. Broudo*, 125 S.Ct. 1627 (2005) ("something beyond the mere possibility of loss causation must be alleged, lest a plaintiff with 'a largely groundless claim' be allowed to 'take up the time of a number of other people, with the right to do so representing an *in terrorem* increment of the settlement value").

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Respectfully submitted,
Defendant Alaunus Pharmaceutical, LLC
By its Attorneys,

/s/ Ryan Ciporkin

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CERTIFICATE OF SERVICE

I, Ryan Ciporkin, hereby certify that, on this 5th day of January 2013, the documents filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF).

/s/ Ryan Ciporkin

Ryan Ciporkin